

IN THE CLAIMS

Please cancel claims 3, 4 and 14 without prejudice or disclaimer. Please amend claims 1, 5, 7, 8, 9, 12 and 13 as indicated:

1. (Currently Amended) A spacer device for the oral administration of a volatile medium containing a medicament, which device comprises a chamber having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth, wherein the chamber is made of a ~~non-metallic antistatic material~~ polyamide and comprises two frustoconical members assembled together coaxially at divergent ends, said inlet and outlet being respectively at opposed convergent ends.

2. (Original) A device according to claim 1, wherein the chamber is made of an antistatic plastics material.

3. CANCELLED

4. CANCELLED

5. (Currently Amended) A device according to claim 1 ~~4~~, wherein the divergent end of one member is received in the divergent end of the other member to provide a substantially air-tight seal.

6. (Original) A device according to claim 5, wherein the said divergent ends have complementary stepped surfaces to provide a close air-tight fit.

7. (Currently Amended) A device according to claim 1 ~~4~~, wherein locking means are provided to lock the two members together in assembled condition.

8. (Currently Amended) An inhaler for dispensing a measured dose of a medicament in a volatile medium, a spacer device for receiving the medium, and means whereby the user can inhale the said medium from the spacer device, wherein the spacer device is made of ~~non-metallic antistatic material~~ polyamide and comprises two frustoconical members assembled together coaxially at their divergent ends, said inlet and outlet being respectively at the opposed convergent ends.

9. (Currently Amended) An inhaler and spacer device according to claim 8, wherein the spacer device is for the oral administration of a volatile medium containing a medicament, which device comprises a chamber having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth, ~~wherein the chamber is made of a non-metallic antistatic material.~~

10. (Original) The use of a non-metallic antistatic space device for the inhalation of a particulate medicament in a volatile medium.

11. (Original) The use according to claim 10, wherein there is substantially little or no deposit of medicament on the inside of the device.

12 (Currently Amended) A method of administering a dose of a fine particulate medicament suspended in a gas, which comprises injecting said dose into a polyamide ~~non-metallic antistatic~~ chamber, the chamber comprising two frustoconical members assembled together coaxially at their divergent ends, said inlet and outlet being respectively at the opposed convergent ends, and inhaling the dose from the chamber.

13. (Currently Amended) A method according to claim 12, wherein the chamber device is in a device having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth, ~~wherein the chamber is made of a non-metallic antistatic material.~~

14. CANCELLED

REMARKS

Claims 1, 2 and 5-13 are pending. Claims 3, 4 and 14 have been cancelled without prejudice or disclaimer. The amendments to claims 1, 5, 7, 8, 9, 12 and 13 are supported by the originally filed claims. No new matter has been entered. The Preliminary Amendment filed concurrently with this application amended the claims coincide substantially with the claims of the parent application (U.S. Appl. No. 09/857,707). Thus, the purpose of this Second Preliminary Amendment is to respond to the Office Action of January 14, 2003 issued in connection with the parent application.

Claims 4-7 stood rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim that which is considered the invention. In response, when the features of claim 4 were incorporated into claim 1, any lack of antecedent basis was corrected.

The claims of the parent application stood rejected under 35 USC § 103(a) as allegedly being unpatentable over WO 93/11817 in view of Altounyan et al. (U.S. Patent No. 4,509,515), optionally in further view of GB 2,299,512. The Office Action noted that the difference between the chamber of WO '817 and the chamber of the present claims is the composition of the chamber. Specifically, the chamber of WO '817 is not a polyamide.

However, Applicants respectfully present that using polyamide gives a superior and unexpected result when compared to other antistatic materials, as described in the attached Affidavit of Sunita Sule (Attachment). A fine particles assessment test, i.e., aerodynamic assessment of fine particle fraction as per BP Addendum 1996 using apparatus A and ten doses (see Specification, beginning in the third full paragraph on page 4) provided the following results:

<u>Material</u>	<u>Respirable Fraction</u>
Polycarbonate	40 - 50 %
Polypropylene	50%
Polyamide	65%

Thus, it can be clearly seen that polyamide gives an unexpectedly substantial superior performance over both polycarbonate and polypropylene, i.e., the specific examples presented in WO '817. Additionally, while WO '817 may also suggest other polyolefins, such other polyolefins, including polyethylene, would give similar results, or possibly worse results as polypropylene. Thus, even if it would have been within the general skill of a worker in the art to select polyamide as the antistatic material for the spacer, polyamide gives an unexpected 30 - 63% increase in the respirable fraction.

As each pending claim recites the spacer being made of polyamide, providing the increase in respirable fraction, reconsideration of the rejection made in the parent application Applicants respectfully present that the present claims are patentable over the combination of references cited in the parent application.

Respectfully submitted,



Thomas P. Pavelko  
Registration No. 31,689

TPP/mat  
Attorney Docket No. TPP 31402A

STEVENS, DAVIS, MILLER & MOSHER, LLP  
1615 L Street, NW, Suite 850  
Washington, D.C. 20036  
Telephone: (202) 785-0100  
Facsimile: (202) 408-5200 or (202) 408-5088

Date: Aug 6, 2003